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DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Care Financing Administration

Refer to: FQA-541

Memorandum

Date MAR 15 1994

From Director
Office of Payment Policy, BPD

Subject Determination of Acquisition Cost of Drugs--INFORMATION

To All Associate Regional Administrators
for Medicare

Medicare regulations (42 CFR 405.517) provide for payment for drugs based on the lower of the estimated acquisition cost or the national average wholesale price (AWP) of the drug. The purpose of this memorandum is to provide instructions on the determination of the acquisition cost of drugs and to provide additional information on other aspects of drug pricing.

We are requesting each carrier to ascertain the acquisition costs for certain high volume drugs for which expenditures exceed $10 million in 1992, including low osmolar contrast materials used in radiology procedures, colony stimulating factors, and EPO (for non-ESRD uses). (See attached listing.) These drugs account for the majority of the total expenditures for drugs. Carriers may, of course, extend their determination of acquisition costs to any other drugs they deem appropriate. Also, carriers who have made cost determinations for drugs need not alter their methodology for determining costs.

Acquisition costs is the cost of that drug to the physician. The invoice from the supplier is the best source of information about how much the drug costs. Sometimes the invoice shows discounts on the purchase of the drugs. However, sometimes discounts are received at the end of a period of time or after a specified number of purchases rather than for each purchase and this is not shown on each invoice.

To help carriers determine acquisition costs for high volume drugs, we suggest that they request copies of the most current invoice from a sample of 5 - 10 physicians who bill for the drugs in question. The sample can be for the entire carrier area, i.e., separate samples are not needed for each locality. Physicians should be asked whether there are any discounts not reflected on the invoices. The median price (net of any discounts) paid by the sampled physicians should be considered the estimated acquisition cost.

HHC903-0913

Defendants' Exhibit
1055
01-12257 - PBS

Carriers should complete these calculations within 60 days of their receiving these instructions. When the carrier has accumulated this information and has determined the estimated acquisition cost, it can start paying claims under the lower of the AWP or estimated acquisition cost policy after first providing physicians with 30 days notice. Carriers should send their payment amounts for the drugs (indicate whether AWP or cost) to their regional offices. You should forward this information to us.

Please remind carriers that in the interim, while they are determining the estimated acquisition cost of the drug, in no case should drugs be paid at an amount greater than AWP. This policy was announced in an All ARA memorandum dated January 14, 1992 (Q and A 18). This survey should be repeated at least annually, or more frequently if there are indications that prices have changed substantially.

Additional Issues:

Determination of AWP - To determine the AWP, calculate the median price of the generic form of the most frequently administered dosage of the drug as reflected in sources such as the Red Book, Blue Book, or Medispan. In calculating the median price, use the price of the smallest unit of packaging offered by the manufacturer that includes the most frequently administered dosage of the drug. Also, brand name products are not included in the array of prices used to determine the cost of multiple source drugs. Only prices for the generic form of the drug are to be used in the calculation of the median price.

Multiple source situations - When calculating the median price for all sources of the generic form, use the payment per dose amount of all sources to determine the median price. If there is a difference in strengths, array that difference separately.

Single source situations - Use the payment per dose amount of the drug. If there is a difference in strengths array that difference separately.

Payment per dose for single dose vials - If a physician uses less than the amount of drug in a single use vial, pay for the cost or AWP of the vial, not the amount actually used. The difference between what is paid for and what is used is the waste. By paying for the cost or AWP of the vial, we are paying for waste directly.

Payment per dose for multiple use vials - The carrier should estimate the "usual" or "average" number of doses that can be extracted routinely from a multiple use vial and divide this number into the cost or AWP of the vial to arrive at the payment per dose.

Additional Costs - Section 405.509 of the regulations permits the carriers to consider additional costs when determining the estimated acquisition costs of a drug. We have been told that for some drugs, notably chemotherapy drugs, physicians may incur additional costs related to the drugs. These costs have been described as overhead costs and include storage, waste, spoilage, breakage, and handling. Some physicians do not incur costs for handling drugs in their offices because they use a drug dispensing service. In addition to the estimated acquisition costs, consider allowing an additional fee for the overhead of handling or dispensing drugs. However, in no case can the payment for the drug plus a dispensing fee exceed the AWP for the drug.

Charles R. Booth

Attachment

cc:
Stewart Streimer, BPO
Field Operations
Office of Issuances

FQA-541:Stan Weintraub/x64498
DATE:February 3, 1994/FINAL:Joan 2/9;2/15;3/15/94
DISC:J11/DOC:PricDrug.sw/FILE CODE:D
Additional Information:Inc BPO's comments;
ARAs via PROFS only

Attachment

J0640	Injection, leucovorin calcium, per 50 mg vial (Wellcovorin)
J7190	Factor VIII (anti-hemophilic factor (human)) per IU, (Hemofil M, Koate-HP, Monoclate-p)
J9010	Doxorubicin HCL, 50 mg vial, (Adriamycin PFS, Adriamycin RDF, Rubex)
J9045	Carboplatin, 50 mg (Paraplatin)
J9182	Etoposide, 100 mg (VePesid)
J9202	Goserelin acetate implant, per 3.6 mg (Zoladex)
J9217	Leuprolide acetate (for depot suspension), 7.5 mg (Lupron)

Colony Stimulating Factors

J1440	Injection, filgrastim (G-CSF), 300 (Neupogen)
J1440	Injection, filgrastim (G-CSF), 480 (Neupogen)
J2820	Injection, sargramostim (GM-CSF), 250 mcg (Leukine, Prokine)

EPO

Q9930	Erythropoietin per 1000 units, at patient Hct of 30

Low Osmolar and Paramagnetic Contrast Materials

A4644	Supply of low osmolar contrast material (100 - 199 mg of iodine)
A4645	Supply of low osmolar contrast material (200 - 299 mg of iodine)
A4646	Supply of low osmolar contrast material (300 - 399 mg of iodine)
A4647	Supply of paramagnetic contrast material (e.g., gadolinium)